

## REMARKS

Claims 3, 5, 11, 13-21, 23 and 24 are pending in the application. All claims are rejected.

Claim 5 is presently amended. Support for the amendment is found in the substitute specification as-filed at page 4, lines 11-13. The amendment is necessary in view of the new grounds of rejection in the present Final Office Action and for this reason could not be presented earlier.

No new matter is introduced and entry of the amendment is respectfully requested.

Rejection Under 35 USC 103(a)

Claims 5, 3, 21, 23 and 24 are rejected under 35 USC 103(a) as allegedly unpatentable over Sakurai et al. (US 4,113, 635), in view of Memita et al. (US 6,939,980), in view of Andrulis Jr. et al. (US 5,654,312), in view of Knothe et al. (American Chemical Society, 1997) and further in view of Linder (US 4,332,702) and Kirk-Othmer (Wiley-Interscience, 1993, vol. 10, 4<sup>th</sup> ed. page 267). It is asserted that Sakurai et al. disclose the invention except for the fatty acid ester mixture of pentaerythritol being incorporated as a wax component in a cosmetic and/or pharmaceutical composition; the fatty acid being a mixture of fatty acids, the weight percentage of C<sub>16</sub> and C<sub>18</sub> fatty acids in the mixture and the fatty acids having 6 to 22 carbon atoms being comprised of unbranched fatty acids. Memita et al. is relied upon for teaching incorporation of a fatty acid ester mixture of pentaerythritol being incorporated as a wax into a cosmetic and/or pharmaceutical composition. Andrulis is relied upon for teaching that a partial fatty acid ester of pentaerythritol monostearate can be used to prepare dermally applicable formulations. Further, Knothe et al. is relied upon for an analysis of the fatty acids of the beef tallow used in Sakurai's Example 3 to support an argument that Sakurai et al. teaches a mixture of fatty acids. Lindner is relied upon for teaching a weight percentage of C<sub>16</sub> and C<sub>18</sub> fatty acids in the mixture which overlaps Applicant's claimed range. Fatty acids containing 6 to 22 carbon atoms comprised of unbranched fatty acids are taught by the combination of Sakurai and Kirk.

It is generally alleged in the office action that there is no proof that Applicant's claimed composition possesses unobvious or unexpected properties differing from the properties of the compositions taught by the combined references. Applicants traverse the rejection.

Independent claim 5, as amended, recites that the esters have a ratio by weight of  $C_{16}/C_{18}$  fatty acid of about 0.7 to 0.9. This particular ratio of  $C_{16}/C_{18}$  fatty acids has been found to provide superior sensory properties to the compositions. *Page 4, lines 11-14, of the substitute specification.* The combination of references relied upon in the rejection does not teach or suggest the ratio of  $C_{16}/C_{18}$  fatty acids claimed nor does it recognize the unexpected properties associated with the recited ratio range. Specifically, formulations containing  $C_{16}/C_{18}$  fatty acids according to the invention exhibited improved phase stability, improved macroscopic/microscopic appearance and improved sensory properties compared to preparations containing greater than 90%  $C_{18}$  fatty acid. *See Table, page 18 of the substitute specification.*

To establish *prima facie* obviousness, a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result- effective variable.). In the present rejection, the combined references fail to recognize the ratio of  $C_{16}/C_{18}$  fatty acids as a result-effective variable with respect to obtaining improved sensory properties in the composition. *Prima facie* obviousness has therefore not been established with respect to claim 5. Withdrawal of the rejection is requested.

Even if the cited references recognized the ratio of  $C_{16}/C_{18}$  fatty acids as affecting sensory properties (and Applicants maintain that they do not), evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed

compound shares with the prior art, can rebut *prima facie* obviousness. "Evidence that a compound is unexpectedly superior in one of a spectrum of common properties . . . can be enough to rebut a *prima facie* case of obviousness." *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987) (Evidence showing that the claimed herbicidal compound was more effective than the closest prior art compound in controlling quackgrass and yellow nutsedge weeds in corn and soybean crops was sufficient to overcome the rejection under 35 U.S.C. 103, even though the specification indicated the claimed compound was an average performer on crops other than corn and soybean.). See also *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (unexpected superior therapeutic activity of claimed compound against anaerobic bacteria was sufficient to rebut *prima facie* obviousness even though there was no evidence that the compound was effective against all bacteria). In the present case, the comparative composition, which does not have the claimed ratio of C<sub>16</sub>/C<sub>18</sub> fatty acids, exhibits some level of phase stability, macroscopic/microscopic appearance and sensory properties, but as shown in the Table on page 18 of the substitute specification these properties are clearly inferior to the composition of the claimed invention. For this additional reason, claim 5 is not obvious over the combined references.

The office action further asserts that Sakurai discloses ranges of partial fatty acid esters that overlap the claimed range and Lindner discloses weight percentages of C16 and C18 fatty acids that overlap the claimed range (paragraphs 17 and 22 of the office action). Although such overlapping ranges can create a case of *prima facie* obviousness, in view of the amendment of claim 5 to recite the ratio of C<sub>16</sub>/C<sub>18</sub> fatty acids, this is not the case for the claimed composition as a whole. However, the unexpected results discussed above with respect to a composition containing the claimed ranges argue against a conclusion of obviousness. *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990); *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004).

Claims 3, 21, 23 and 24 depend, directly or indirectly, from independent claim 5. If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending

therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Accordingly, withdrawal of the rejection of claims 3, 21 23 and 24 is requested.

Claims 11 and 13-20 are rejected under 35 USC 103(a) as allegedly unpatentable over Sakurai et al. (US 4,113, 635), in view of Memita et al. (US 6,939,980), in view of Andrulis Jr. et al. (US 5,654,312), and further in view of Linder (US 4,332,702) and even further in view of Plough, Inc. (EP 0179416), and Bauer et al. (WO 2003/028690A; 2004/0258721).

Claims 11 and 13-20 also depend directly or indirectly from independent claim 5, and are therefore patentable as discussed above. In addition, the Examiner has not pointed to anything in Plough, Inc. or Bauer that would overcome the failure of the remaining references to recognize the ratio of C<sub>16</sub>/C<sub>18</sub> fatty acids as a result-effective variable impacting the sensory properties of the composition. Withdrawal of the rejection of claims 11 and 13-20 is therefore also requested.

#### CONCLUSION

Applicants submit that claims 3, 5, 11, 13-21, 23 and 24 of the present patent application are now in condition for allowance, and an action passing this case to issue is respectfully requested. It is believed that no fees are due in connection with this submission, however, if fees are found to be due, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned by telephone if there are any issues remaining in this case.

Respectfully submitted,

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/Donna R. Fugit, Reg. No. 32,135/  
Donna R. Fugit, Ph.D.  
Reg. No. 32,135

DIEHL SERVILLA LLC  
33WOOD AVENUE SOUTH, SUITE 210  
ISELIN, NEW JERSEY 08830  
(732) 815-0404  
FAX (732) 815-1330